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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,013

12/23/2005

Francesco Makovec

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EXAMINER

CHO, JENNIFER Y

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

04/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,013	Applicant(s) MAKOVEC ET AL.	
	Examiner JENNIFER Y. CHO	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 4-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Receipt is acknowledged of the Response filed 12/3/07.

Claims 1-2, 4-14 are considered to be the elected invention. Claim 3 has been cancelled.

Receipt is acknowledged of the 1.132 Declarations filed 3/18/08 and 12/3/07.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 and 4-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Makovec et al. (US 5,130,474), in view of Midler et al. (US 5,314,506). For reasons, see previous office action and responses stated herein.

Response to Arguments

Applicant's arguments have been considered but are not persuasive for the following reasons:

The Examiner acknowledges Applicant's argument that Midler et al. teaches achieving particles sizes of compounds having a diameter equal or less than 25 μm .

In response, the Examiner points out that Applicant's claims are drawn to less than 15% of the compounds having a particle size less than 10 μm , not 25 μm .

Furthermore, the Applicant has not shown any unexpected results for compounds with particle sizes larger than 25 μm versus compounds with particle sizes less than 10 μm . The Examiner is not convinced that this small difference in particle size would result in superior physical properties for the preparation of pharmaceutical forms for oral use.

The Examiner acknowledges Applicant's argument that the crystallization method for the preparation of dexloxiglumide provides substantial advantages both in qualitative terms (rheological properties of the obtained product) and in quantitative terms (yield increase).

With respect to the qualitative and quantitative advantages, the Examiner points to the teaching of Makovec et al. which teaches the equivalency of recrystallizing with isopropyl ether and water/alcohol (columns 5 and 6, table 3, see solvents of crystallization column), and to the teaching of Midler et al. which teaches recrystallizing in ethers generally (column 5, line 18), along with seeding the solution (column 7, line 51). Thus because the art teaches the same process steps, the art reads on Applicant's claims, and it would be obvious to one of ordinary skill in the art to obtain the same rheological properties and yields for the preparation of dexloxiglumide, employed by the same process steps. Furthermore, it would be standard procedure to optimize these properties and yields to one of ordinary skill in the art.

The Examiner acknowledges the 1.132 Declaration, in which the Applicant has compared an example of recrystallization with seeding and without seeding.

With respect to the Declaration, the Examiner does not find the Declaration convincing, especially in light of the teaching of Midler et al. which teaches seeding and recrystallization in ether solvents. The Applicant has not compared examples in which the seeding was done using crystals greater than 20 μm versus seeding done with crystals less than 20 μm .

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use the seeding and recrystallization method of Midler et al. for the purification method of Makovec et al. to prepare dexloxiglumide with good rheological properties and high yield. The expected result would be the efficient production of pure dexloxiglumide for the pharmaceutical industry.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Cho
Patent Examiner
Art Unit: 1621

/SHAILENDRA - KUMAR/
Primary Examiner, Art Unit 1621